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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,009	12/31/2003	Samuel P. McManus	SHE0074.00	5509

21968 7590 06/28/2006

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/751,009	<b>Applicant(s)</b> MCMANUS ET AL.	
	<b>Examiner</b> James W. Rogers, Ph.D.	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-53, 170-182, 184, 187 and 188 is/are pending in the application.
- 4a) Of the above claim(s) 37, 40, 46, 50, 51, 170-182, 184 and 187-188 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35, 47 and 52 is/are rejected.
- 7) ☒ Claim(s) 36, 38, 39, 41-45, 48, 49 and 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/18/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I in the reply filed on 05/15/2006 is acknowledged. The traversal is on the ground(s) that a combined search of both Group I and Group II does not impose an undue burden on the examiner. This is not found persuasive because even though the two groups are classified in the same group they are not classified in the same subgroup and invention II is a method for making a polymer active conjugate which contains an active agent conjugated to the water soluble polymer segment not required in invention I thus they would comprise a different search and therefore be burdensome on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

The examiner also notes the election of species comprised of a keto-piperidinyl group, a linear PEG and methyl as a specific R<sup>7</sup>. The examiner could find no relevant art on linear PEG substituted with a keto-piperidinyl group, therefore the examiner searched the broader definition of claim 35 for the type of functional group that is part of a cyclic structure which is attached to the water-soluble polymer. The examiner could also find no relevant art for the non-elected species in claims 36,37 and 53.

### ***Claim Objections***

Claims 36,38-39,41-45,48-49 and 53 are objected to for depending on a rejected claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35,47 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (US 2001/0011115 A1).

Harris teaches PEG derivatives with proximal reactive groups which includes N-succinimydyl which would satisfy a functional group (ketone) attached to a cyclic ring (pyrrolidine). See abstr. [0041], [0046], [0051], [0053]. Regarding claim 52 the limitation is met because the cyclic structure is an aza form of a cyclopentyl group.

Claims 35,47 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Harris et al. (US 6,348,558 B1).

Harris teaches PEG derivatives with proximal reactive groups which includes N-succinimydyl which would satisfy a functional group (ketone) attached to a cyclic ring (pyrrolidine). See abst, col 2 lin 33-63.

Claims 35,47 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Bentley et al. (US 6,448,369 B1).

Bentley teaches PEG derivatives with proximal reactive groups which includes N-succinimydyl which would satisfy a functional group (ketone) attached to a cyclic ring (pyrrolidine). See abst, col 5 lin 15- col 7 lin 43.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35,47 and 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No. 6,348,558 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim PEG derivatives with proximal reactive groups that may contain a cyclic structure with a functional group.

Claims 35,47 and 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 8 of U.S. Patent No.

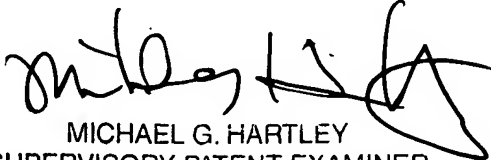
6,488,369 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim PEG derivatives with proximal reactive groups that may contain a cyclic structure with a functional group. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim PEG derivatives with proximal reactive groups that may contain a cyclic structure with a functional group.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER